REMARKS

The application has been amended to correct minor informalities and to more particularly point out and distinctly claim the subject matter that Applicants regard as the invention so as to place the application, as a whole, into a *prima facie* condition for allowance. Great care has been taken to avoid the introduction of new subject matter into the application as a result of the foregoing modifications.

Claims 1-26 are pending in the present application. By way of the foregoing, Claims 1, 11, 12, and 23-25 have been amended to more particularly point out and distinctly claim the subject matter that Applicants regard as the invention. Specifically, the claims have been amended to correct minor informalities and to identify the uniformity and reproducibility of the sample material achieved via its treatment by the claimed invention. Support for the claim amendments is found throughout the specification and originally filed claims, and thus no new matter is added.

I. Claim Rejections under 35 U.S.C. § 112

In the present action, the Examiner rejected Claims 24 and 26 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Examiner's rejection of Claims 24 and 26 under 35 U.S.C. § 112, second paragraph, have been obviated by the foregoing amendment. Specifically, Claim 24, as amended, recites a proper antecedent basis for the terms "the components" and a more definite reference for "means for connecting." Claim 25 is amended to clarify the claimed range such that Claim 26, depending therefrom, is now within the recited range. Accordingly, in light of the foregoing amendment, Applicants respectfully request withdrawal of the rejections of Claims 24 and 26 under 35 U.S.C. § 112, second paragraph.

II. Claim Rejections under 35 U.S.C. § 102

In rejecting Claims 1-6 and 8 under 35 U.S.C. § 102(e) as being anticipated by Gautsch et al., the Examiner points out that Gautsch et al. disclose a process and apparatus for treating materials in containers including vibrating containers to provide for a horizontal and vertical movement of the containers. To support this point, the Examiner references Figures 1-4 of Gautsch et al. The apparatus of Gautsch et al. teaches a disruption device for fracturing tissues and cell walls by mechanically reciprocating a container of tissue and liquid medium to elicit the release of the components of the tissues and cells, and in particular, release of nucleic acid molecules, into the liquid medium. However, Gautsch et al. do not disclose or teach a process or device for macerating solid material that yields a reproducible and uniform product, and therefore, Applicants disagree with the present ground of rejection under Section 102.

The present claimed invention, in contrast to Gautsch et al., claims a device for macerating solid material that yields a reproducible and uniform product. Furthermore, the present claimed invention adds the limitation of pulverizing solid sample material. Clearly, Gautsch et al. do not teach or suggest pulverization of materials. In contrast, Gautsch et al. teach the preservation of products released from the cell and into the liquid medium during disruption. The present claimed invention requires that the sample material processed in the claimed device yields a reproducible and uniform macerated product. Accordingly, Gautsch et al. cannot support a rejection of the present claimed invention under 35 U.S.C. § 102(e) and Applicant respectfully requests withdrawal of the rejections based on the same.

The Court of Appeals for the Federal Circuit ("CAFC") and its predecessor court have had numerous opportunities to interpret the statutory language of 35 U.S.C. § 102.

Issues relating to the anticipatory nature of prior art under Section 102 are therefore resolved by applying the precedent established and adopted by the CAFC. In terms of identifying what anticipation is, the court has stated that,"[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). In terms of identifying what an anticipating reference is, the court has stated that, "[t]o be prior art under section 102 the reference must put the anticipatory subject matter at issue into the possession of the public through an enabling disclosure." *Chester v. Miller*, 15 USPQ2d 1333, 1336 n.2 (Fed. Cir. 1990). In other words, "[a] reference cannot anticipate that which it does not enable." *University of California v. Eli Lilly and Co.*, 39 USPQ2d 1225, 1242 (S.D. Ind. 1995), *aff'd*, 43 USPQ2d 1398 (Fed. Cir. 1997), *cert. denied*, 118 S. Ct. 1548 (1998).

By applying the above-stated CAFC rules for interpreting prior art under 102, it becomes evident that the Gautsch et al. reference cannot stand as an anticipating prior art reference. First, each and every element as set forth in Claims 1-6 and 8 is not found, either expressly or inherently, in the Grand et al. reference. *Verdegaal Bros.*, 2 USPQ2d at 1053. Gautsch et al. teach a disruption device for fracturing tissues and cell walls by mechanically reciprocating a container of tissue and liquid medium to elicit the release of the components of the tissues and cells, and in particular, the release of nucleic acids, into the liquid medium. [Gautsch et al., Column 2, Lines 8-20]. Gautsch et al. do not teach or suggest pulverization of materials. Despite the Examiner's assertion that the teachings of Gautsch et al. anticipate the methods of Claims 1-6 and 8, such a statement does not satisfy the "inherent" or "express" quality of an anticipating disclosure as required by the CAFC. *Verdegaal Bros.*, 2 USPQ2d at 1053.

The foregoing amendment to the claims further distinguishes Applicant's invention from that disclosed in the prior art so as to place the present application in a condition whereby it is not anticipated by Gautsch et al. Furthermore, Gautsch et al. is a reference that cannot anticipate Claims 1-6 and 8 because Gautsch et al. cannot anticipate that which it does not enable. *University of California*, 39 USPQ2d at 1242. While Gautsch et al. do teach a disruption device for fracturing tissues and cell walls by mechanically reciprocating a container of tissue and liquid medium to elicit the release of the components of the tissues and cells into the liquid medium, Gautsch et al. do not disclose or teach a process or device for macerating solid material that yields a reproducible and uniform product. Accordingly, Applicants respectfully request that the Examiner withdraw the rejection of Claims 1-6 and 8 under 35 U.S.C. § 102(e).

III. Claim Rejections under 35 U.S.C. § 103

Claims 25 and 26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Moore et al. Applicants respectfully disagree with this ground of rejection and submit that Moore et al. does not render obvious Applicants' invention. The Examiner points out that Moore et al. disclose the basic process steps of treating material in sample containers by rapidly moving the containers in both horizontal and vertical directions within an arcuate flow path. According the Examiner, adding to the number of containers used within the process of Moore et al. and the means to support additional containers would have been obvious to one of ordinary skill in the art. Moreover, the apparatus of Moore et al. teaches an agitation device for breaking bacterial cells while dissipating heat to prevent the destruction of proteins and enzymes released during cell agitation. However, Moore et al. do not disclose or teach a process or device for macerating solid material that yields a reproducible and uniform product.

The present claimed invention, in contrast to Moore et al., claims a device for macerating solid material that yields a reproducible and uniform product. Furthermore, the present claimed invention adds the limitation of pulverizing solid sample material. Clearly, Moore et al. do not teach or suggest pulverization of materials. In contrast, Moore et al. teach the preservation of products released from the cell during agitation. The present claimed invention requires that sample material processed in the claimed device yields a reproducible and uniform macerated product.

While Moore et al. do teach an agitation device for breaking bacterial cells while dissipating heat to prevent the destruction of proteins and enzymes released during the cell agitation, Moore et al. do not disclose or teach a process or device for macerating solid material that yields a reproducible and uniform product. Accordingly, Moore et al. cannot support a rejection of the present claimed invention under 35 U.S.C. § 103(a) and Applicants respectfully request withdrawal of the rejections based on the same.

The Examiner next rejected Claims 7 and 9-26 under 35 U.S.C. § 103(a) as being unpatentable over Gautsch et al. Applicants respectfully disagree with this ground of rejection and submit that Gautsch et al. does not render obvious Applicants' invention. The Examiner points out that Applicants' invention is merely a collection of design choices made in modification of Gautsch et al. The apparatus of Gautsch et al. teaches a disruption device for fracturing tissues and cell walls by mechanically reciprocating a container of tissue and liquid medium to elicit the release of the components of the tissues and cells, and in particular, the release of nucleic acid molecules, into the liquid medium. However, Gautsch et al. do not disclose or teach a process or device for macerating solid material that yields a reproducible and uniform product.

The present claimed invention, in contrast to Gautsch et al., claims a device for macerating solid material that yields a reproducible and uniform product. Furthermore,

the present claimed invention adds the limitation of pulverizing solid sample material. Clearly, Gautsch et al. do not teach or suggest pulverization of materials. In contrast, Gautsch et al. teach the preservation of products released from the cell during disruption. The present claimed invention requires that sample material processed in the claimed device yields a reproducible and uniform macerated product.

While Gautsch et al. do teach a disruption device for fracturing tissues and cell walls by mechanically reciprocating a container of tissue and liquid medium to elicit the release of the components of the tissues and cells, and in particular, the release of nucleic acids into the liquid medium, Gautsch et al. do not disclose or teach a process or device for macerating solid material that yields a reproducible and uniform product. Accordingly, Gautsch et al. cannot support a rejection of the present claimed invention under 35 U.S.C. § 103(a) and Applicants respectfully request withdrawal of the rejections based on the same.

Accordingly, the purpose of the claimed invention is not taught or suggested by the cited references, nor is there any suggestion or teaching that would lead one skilled in the relevant art to combine references in a manner that would meet the purpose of the claimed invention. Because the cited references, whether considered alone, or in combination with others, do not teach or suggest the purpose of the claimed invention, Applicants respectfully submit that the claimed invention, as amended, patentably distinguishes over the prior art, including the prior art cited merely of record.

Based on the foregoing, Applicants respectfully submit that Claims 1-26, as amended, are in condition for allowance at this time, patentably distinguishing over the cited prior art. Accordingly, reconsideration of the application and passage to allowance are respectfully solicited.

The Examiner is respectfully urged to called the undersigned attorney at (919) 425-3000 to discuss the claims in an effort to reach mutual agreement with respect to claim limitations in the present application which will be effective to define the patentable subject matter if the present claims are not deemed adequate for their intended purpose.

Respectfully submitted,

Dated: MAY 13, 2003

Timothy G. Hofmeyer
Registration No. 46,777
Paradigm Genetics, Inc.
108 Alexander Drive
Post Office Box 14528
Research Triangle Park, NC 27709-4528
Telephone: (919) 425-3000

Attorney for Applicants

Customer No. 022881